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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,102	05/01/2001	Dennis A. Carson	066778-0397	5759

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/847,102	CARSON ET AL.	
	Examiner	Art Unit	
	MISOOK YU	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,16,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,16,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2007 has been entered.

Claims 1-8, 16, 28, and 29 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112, Maintained

Claims 1-8, 16, 28, and 29 **remain rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because applicant's argument is persuasive. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the specification at page 22 lines 3-6 explicitly define "modulating a biological activity of a malignant cell" to include "cell growth inhibition" and "ability to elicit a cytotoxic response" to the malignant cells.

These arguments have been fully considered but found unpersuasive because the specification at pages 21-22 reasonably communicates anti-Fz ab that blocks Wnt protein binding to their receptors via antibodies directed to the extracellular portion of frizzed receptors would be used for modulating a biological activity of a malignant cell and these antibodies are used to "cell growth inhibition" and "ability to elicit a cytotoxic response" to the malignant cells. The original claim 10 recites ten different SEQ ID Nos, all belong to frizzed receptors. However, the specification as originally filed does not specifically point out the antibody to SEQ ID NO: 68 would have the activity. Rather, the specification as originally filed points out frizzled 2 antibody, not frizzled 5 antibody have such activities. Note Fig. 5 and 6.

Claim Rejections - 35 USC § 103

Claims 1-8, 16, 28, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (IDS, #1711998, Proc. Natl. Acad. Sci. USA. vol. 95, pages 10164-9) in view of US Pat. 5,677,171 (IDS, Hudziak et al., Oct. 14, 1997).

Claims 1-8, 16, 28, and 29 are drawn to a purified antibody binds to an epitope at the N-terminal extracellular domain (SEQ ID NO: 68) or pharmaceutical comprising said antibody, wherein the antibody inhibits growth of a malignant cell expressing a frizzled 5 receptor.

Applicants argues that the cited references provide no motivation to modify their combined teachings with a reasonable expectation of success with regard to pursuing frizzled 5 as a target for inhibition of malignant cell growth or immunotherapy. Applicant also argues that Tanaka reference teaches away from away from the claimed invention

because the reference only teaches Frizzled 3 being expressed in the cancer but not Frizzled 5 .

These arguments have been fully considered but found unpersuasive. Tanaka et al., were cited to show that recited SEQ ID NO: 68 is not applicant's discovery, but Tanaka et al's discovery as shown at note page 10164, right column under the heading Cloning of the Human FZ Genes, and also page 10165, left column under the heading "Identification of Human Esophageal Carcinoma-Specific Fz Gene. Note the sequence alignment provided with the Office action mailed on 08/04/2003. Tanaka et al., at the paragraph bridging pages 10164-5 teach that N-terminal extracellular domain of a frizzled receptor lies just before the first transmembrane helix, also teach "the ectodomain of Fz functions as natural antagonist of Fz-mediated signal transduction". Tanaka et al., at page 10164 teach Wnt binds to Frizzled family of seven-transmembrane proteins, and the seven-transmembrane proteins frizzled family proteins act as receptors for "Wnt oncoprotein" (see page 10164, left column). Note this teaching with the teachings of the instant specification at page 21-22: it is almost identical. Thus, teaching of Tanaka et al., suggest frizzled member proteins in tumor development and importance of extracellular domain of frizzled receptor for receptor-mediated signal for wnt-mediated oncogenic process. The disclosure of Tanaka et al., is similar in that the instant specification discloses frizzled 2 data (Fig. 5 and 6), while Tanaka et al., discloses frizzled 3 data. Both the instant application and Tanaka et al., connects any Frizzled to Wint signaling in terms of cancer development or cancer therapeutics.

As applicant argument that Hudziak patent is not about Frizzled 5 protein, Hudziak patent is cited to show that antibodies to a receptor has been used to inhibit the growth of tumor cells (column 5, lines 16 and 17) in the art and making and screening such antibodies are well within the knowledge of the ordinary skill in the art. Hudziak patent teaches that antibodies are selected using conventional in vitro assays for selecting antibodies which neutralize receptor function. This suggests that an antibody binding to extracellular domain, where the natural ligand binds to, would inhibit the function of the receptor. Hudziak patent also teaches assays to screen an antibody that inhibits growth of the malignant cell. Hudziak patent teaches a cytotoxic response and label at claims 1-39.

Therefore one of ordinary skill would have been motivated to screen an antibody binding to the extracellular domain (i.e. the natural ligand binding site) of frizzled 5 protein, which is expressed on a malignant cell as taught by Tanaka et al., wherein the antibody inhibits the growth of the malignant cells since the screening assay is taught by Hudziak patent. It would have been obvious to one of ordinary skill in the art to make and use an antibody directed the extracellular domain of a receptor because of the advantage as taught by the Hudziak patent. Further, one of ordinary skill would be motivated to screen an antibody inhibiting cancer cells because this kind of antibody could be used in cancer treatment as taught by Hudziak patent, and cancer treating antibody would make money.

In addition, based on Noelle v. Lederman, 69 USPQZd 1508, 1514 (Fed. Cir. 2004), an antibody to known antigenic sequence is obvious, and one of skill would have

been arrived at the claimed invention with a reasonable expectation of success, given the amino acid sequence has been known, the extracellular domain of a frizzled 5 is where the natural ligand binds to, had been well known in the art before the effective filing date of the instant application as taught by Tanaka et al., and also given that advantage of the antibody to extracellular domain and an assay to isolated an antibody inhibiting the growth of a malignant cell had been known in the art as taught by Hudziak patent well before the effective filing date of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

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